REMARKS

The present invention relates to novel cancer vaccines. More particularly, the invention relates to using hapten-modified tumor cells to elicit an anti-tumor T cell response in a cancer patient thereby providing a therapeutic benefit. Claims 2, 6 and 22 are currently pending in the application, and claim 2 is currently amended herein. Support for the amendment to claim 2 can be found throughout the application, for example, on page 43, line 21-26. Claims 1, 4-5, 7-8 and 23-24 have been canceled. Claims 3 and 9-21 have been withdrawn.

Rejections

(1) Claims 2, 6 and 22 stand rejected in the Office Action under 35 U.S.C. §112, first paragraph, for lacking enablement. The Office Action states that the recitation "in a state of no growth" reads on attenuated cells, which would be expected to return to a growth phase at some point in their life cycle.

(2) Claims 2, 6 and 22 stand rejected under 35 U.S.C. §103(a) for being obvious in view of Hoover, et al. (Cancer 55:1236-1243 (1985)) and U.S. Patent No. 5,290,551 ("the '551 patent"). The Office Action states that Hoover et al. teach treatment of colon carcinoma using a vaccine that includes colon carcinoma cells and BCG as an adjuvant, and the '551 patent teaches treatment of melanoma with a haptenized melanoma cell vaccine.

Responses

With regard to rejection (1), while not necessarily agreeing with the Examiner, solely in an effort to expedite prosecution of this matter, Applicant has amended claim 2 to recite that the tumor cells used in the method of claim 2 are irradiated. Applicant contends that the Examiner's rejection is rendered moot by this amendment. Applicant requests reconsideration and withdrawal of the rejection.

With regard to rejection (2), while not necessarily agreeing with the Examiner, solely in an effort to expedite prosecution in this matter, Applicant has amended claim 2 to recite that the method also includes a single dose administration of cyclophosphamide prior to administration of the vaccine composition of the present invention (see for example, page 43, lines 21-26).

The Examiner is required to show a *prima facie* case of obviousness when making a rejection under 35 U.S.C. §103(a) (see MPEP §2142). To establish a *prima facie* case of

obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. MPEP § 2142.

Applicant contends that all of the claim limitations are not taught by the combination of Hoover et al. and the '551 patent. Neither Hoover et al. nor the '551 patent teaches or suggests a single administration of cyclophosphamide prior to repeated vaccine administration. In fact, Hoover et al. does not disclose use of cyclophosphamide at all in administering a vaccine of non-haptenized tumor cells, and the '551 patent teaches administration of cyclophosphamide prior to each administration of a vaccine of haptenized tumor cells. Therefore, all of the claim limitations are not taught by the combination of references.

Applicant further argues that the use of cyclophosphamide prior to each administration of the haptenized melanoma vaccine taught in the '551 patent teaches away from administering a single dose of the cyclophosphamide prior to repeated administrations of the haptenized colon carcinoma vaccine of the present invention. In the '551 patent, and in particular, in each of the Examples in the '551 patent, it states that the treatment sequence of cyclophosphamide followed by administration of the vaccine three days later, is repeated every 28 days. Therefore, it was thought, at the time the '551 patent was written, that administration of cyclophosphamide was required prior to each administration of a haptenized melanoma cell vaccine. Thus, a person of skill in the art, armed with the '551 patent, would reasonably believe that cyclophosphamide administration is necessary prior to each administration of a haptenized tumor cell vaccine.

For the reasons discussed above, the combination of Hoover et al. with the '551 patent cannot render claims 2, 6 and 22, as amended, *prima facie* obvious under 35 U.S.C. § 103(a) and, therefore, Applicant requests that the rejection be reconsidered and withdrawn.

Summary

Applicant respectfully submits that each rejection of the Examiner to the claims of the present application has been either overcome or is now inapplicable, and that each of claims 2, 6, and 22, is in condition for allowance. Reconsideration and allowance of each of these claims are respectfully requested at the earliest possible date.

Respectfully submitted,
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Enclosure: Petition for three month extension of time and authorization to charge fee